K092730

REVISED

510(k) SUMMARY NOV 2 0 2009

As required by the Safe Medical Devices Act of 1990

DESCRIPTION OF THE APPLICANT DEVICE

TRADE NAME: BRUSHABLE COMPOSITE
COMMON NAME: Brushable Dental Composite
CLASSIFICATION NAME: Tooth Shade Resin Material (21 CFR 872.3690, Product code EBF)

Indications for Use: Cosmedent BRUSHABLE COMPOSITE is used to facilitate the brush/instrument application of dental composite restorative materials; to assist in direct veneering of anterior teeth, splinting, and repair of composite restorations. BRUSHABLE COMPOSITE may be used during layering especially if the air-inhibited surface has been affected.

The technological characteristics of the applicant device are essentially identical to the predicate device.

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

TRADE NAME: Bisco SCULPTING RESIN
COMMON NAME: Brushable Dental Composite
CLASSIFICATION NAME: Tooth Shade Resin Material (21 CFR 872.3690, Product code EBF)
510(k) Number: K030585

SUBSTANTIAL EQUIVALENCE SUMMARY

EQUIVALENTS	Cosmedent BRUSHABLE COMPOSITE	Bisco Sculpting Resin
	Similarities	
Intended Use	Both products are intended to be used to manipulate and sculpt esthetic dental restorative materials	
Composition	Both products have substantially the same chemical composition. They are light-cure, silica filled, difunctional acrylic composites	
Physical/mechanical Aspects	Both products are low viscosity microfilled composites and have similar physical and mechanical properties	
How supplied and used	Both products are supplied as preloaded, plastic syringes. The material is extruded onto a suitable pad or well and applied to the instrument	
	Differences	
Filler percentage	36%	30%

Submitted by: James L. Sandrik, PhD
Cosmedent, Inc.
401 N. Michigan Ave. Suite 2500
Chicago, IL 60611

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

NOV 20 2009

James L. Sandrik, Ph. D
Director of Regulatory Affairs
Cosmedent, Incorporated
401 North Michigan Avenue, Suite 2500
Chicago, Illinois 60611

Re: K092730
Trade/Device Name: Brushable Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: November 3, 2009
Received: November 4, 2009

Dear Dr. Sandrik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

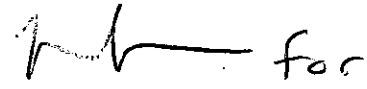
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

REVISED

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: MULTIPLE (BRUSHABLE COMPOSITE)

Indication For Use:

BRUSHABLE COMPOSITE is used to facilitate the brush/instrument application of dental composite restorative materials; to assist in direct veneering of anterior teeth, splinting, and repair of composite restorations. BRUSHABLE COMPOSITE may be used during layering especially if the air-inhibited surface has been affected.

Prescription Use___X___ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey for MSL
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092730